

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application:

LISTING OF CLAIMS:

1. (Currently Amended) The method of producing dosage units of a solid drug form containing as the active substance warfarin sodium salt in an amount of 1 to 10 mg and having high a degree of content uniformity meeting Bergum criterion, ~~characterized in that~~ wherein a required amount of an aqueous solution of warfarin sodium salt and/or its clathrate which optionally contains in the dissolved state one of pharmaceutically acceptable excipients co-forming the solid drug form to be prepared but not all the pharmaceutically acceptable excipients co-forming the solid drug form to be prepared, is brought into contact with solid particles of at least one pharmaceutically acceptable excipient co-forming the solid drug form to be prepared, whereupon optionally the particles are dried and optionally mixed with the required amount of solid particles of the remaining pharmaceutically acceptable excipients co-forming the solid drug form to be prepared, and the thus-obtained particulate mixture is formulated into dosage units of the solid drug form.

2. (Currently Amended) The method according to claim 1, ~~characterized in that~~ wherein the bringing into contact of an aqueous solution of warfarin sodium salt and/or its clathrate with solid particles of at least one pharmaceutically acceptable excipient is performed by spraying this solution onto these solid particles.

3. (Currently Amended) The method according to claim 1, wherein ~~or 2,~~
~~characterized in that~~ the aqueous solution of warfarin sodium salt and/or its clathrate
contains 1 to 50 % by weight ~~[[,]] preferably 8 to 35 % by weight,~~ of warfarin sodium
salt and/or its clathrate, based on the weight of the solution.

4. (Currently Amended) The method according to ~~any of claims 1 to 3,~~
~~characterized in that~~ claim 1, wherein the aqueous solution of warfarin sodium salt
and/or its clathrate contains, ~~beside~~ besides water, solely warfarin sodium salt and/or
its clathrate.

5. (Currently Amended) The method according to ~~any of claims 1 to 4,~~
~~characterized in that~~ claim 1, wherein the solid particles of at least one
pharmaceutically acceptable excipient intended for bringing into contact with
aqueous solution of warfarin sodium salt and/or its clathrate, have such particle
distribution that the size of at least 90 % of these particles is greater than 40
micrometers, the size of at most 10 % of these particles is greater than 250
micrometers, and 100 % of these particles are of a size not exceeding 300
micrometers.

6. (Currently Amended) The method according to ~~any of claims 1 to 5,~~
~~characterized in that~~ claim 1, wherein the pharmaceutically acceptable ingredients
are ~~selected from a group consisting of a hydrophilic sugar, preferably sucrose,~~
~~sorbitol, mannitol or lactose, natural or modified starch and cellulose, the most~~

~~preferred being a mixture of lactose and microcrystalline cellulose in a weight ratio 10 : 5 to 11 : 5.~~

7. (Currently Amended) The method according to ~~any of claims 1 to 6,~~
~~characterized in that~~ claim 1, wherein the solid particles of at least one
pharmaceutically acceptable excipient, intended for bringing into contact with
aqueous solution of warfarin sodium salt and/or its clathrate, contain added solid
particles of a pharmaceutically acceptable excipient of a specific surface area of at
least $150 \text{ m}^2.\text{g}^{-1}$ in an amount of 0.1 to 2 % by weight based on the total weight of
solid particles of at least one pharmaceutically acceptable excipient and the said
added ingredient intended for bringing into contact with aqueous solution of warfarin
sodium salt and/or its clathrate, preferably added colloidal silicon oxide, in an amount
of 0.5 % by weight based on the total weight of solid particles of at least one
pharmaceutically acceptable excipient and the said added ingredient intended for
bringing into contact with aqueous solution of warfarin sodium salt and/or its
clathrate.

8. (Currently Amended) The method according to ~~any of claims 1 to 7,~~
~~characterized in that~~ claim 1, wherein the mixture of solid, optionally dried particles,
obtained after spraying an aqueous solution of warfarin sodium salt and/or its
clathrate onto solid particles of at least one pharmaceutically acceptable excipient, is
mixed with at least one pharmaceutically acceptable lubricant such as preferably
magnesium stearate, zinc stearate, aluminium stearate, colloidal silicon oxide,
stearic acid, sodium stearyl fumarate, polyethylene glycol or sodium lauryl sulfate,

used in an amount of 0.1 to 10 % by weight based on the weight of the obtained mixture, preferably with magnesium stearate used in an amount of 1 % by weight based on the weight of the mixture obtained.

9. (Currently Amended) The method according to ~~any of claims 1 to 8,~~ characterized in that claim 1, wherein the mixture of solid, optionally dried particles, obtained after spraying an aqueous solution of warfarin sodium salt and/or its clathrate onto solid particles of at least one pharmaceutically acceptable excipient, is mixed with at least one pharmaceutically acceptable disintegrant such as preferably ultraamylpectin, sodium salt of crosslinked carboxymethylcellulose or crosslinked polyvinylpyrrolidone, used in an amount of 1 to 7 % by weight, based on the weight of the mixture obtained, preferably with sodium salt of crosslinked carboxymethylcellulose, used in an amount of 2 % by weight based on the weight of the mixture obtained.

10. (Currently Amended) The method according to ~~any of claims 1 to 9,~~ characterized in that claim 1, wherein the obtained particulate mixture is formulated into dosage units of solid drug form by filling into capsules and/or sachets, and/or by pressing to tablets.

11. (New) The method according to claim 2, wherein the aqueous solution of warfarin sodium salt and/or its clathrate contains 1 to 50 % by weight of warfarin sodium salt and/or its clathrate, based on the weight of the solution.

12. (New) The method according to claim 2, wherein the aqueous solution of warfarin sodium salt and/or its clathrate contains, besides water, solely warfarin sodium salt and/or its clathrate.

13. (New) The method according to claim 3, wherein the aqueous solution of warfarin sodium salt and/or its clathrate contains, besides water, solely warfarin sodium salt and/or its clathrate.

14. (New) The method according to claim 2, wherein the solid particles of at least one pharmaceutically acceptable excipient intended for bringing into contact with aqueous solution of warfarin sodium salt and/or its clathrate, have such particle distribution that the size of at least 90 % of these particles is greater than 40 micrometers, the size of at most 10 % of these particles is greater than 250 micrometers, and 100 % of these particles are of a size not exceeding 300 micrometers.

15. (New) The method according to claim 3, wherein the solid particles of at least one pharmaceutically acceptable excipient intended for bringing into contact with aqueous solution of warfarin sodium salt and/or its clathrate, have such particle distribution that the size of at least 90 % of these particles is greater than 40 micrometers, the size of at most 10 % of these particles is greater than 250 micrometers, and 100 % of these particles are of a size not exceeding 300 micrometers.

16. (New) The method according to claim 4, wherein the solid particles of at least one pharmaceutically acceptable excipient intended for bringing into contact with aqueous solution of warfarin sodium salt and/or its clathrate, have such particle distribution that the size of at least 90 % of these particles is greater than 40 micrometers, the size of at most 10 % of these particles is greater than 250 micrometers, and 100 % of these particles are of a size not exceeding 300 micrometers.

17. (New) The method according to claim 1, wherein the pharmaceutically acceptable ingredients are selected from at least one of the groups consisting of sucrose, sorbitol, mannitol, lactose, natural starch, modified starch, and cellulose.

18. (New) The method according to claim 1, wherein the pharmaceutically acceptable ingredients are a mixture of lactose and microcrystalline cellulose in a weight ratio of 10:5 to 11:5.

19. (New) The method according to claim 2, wherein the solid particles of at least one pharmaceutically acceptable excipient, intended for bringing into contact with aqueous solution of warfarin sodium salt and/or its clathrate, contain added solid particles of a pharmaceutically acceptable excipient of a specific surface area of at least $150 \text{ m}^2 \cdot \text{g}^{-1}$ in an amount of 0.1 to 2 % by weight based on the total weight of solid particles of at least one pharmaceutically acceptable excipient and the said added ingredient intended for bringing into contact with aqueous solution of warfarin sodium salt and/or its clathrate, preferably added colloidal silicon oxide, in an amount

of 0.5 % by weight based on the total weight of solid particles of at least one pharmaceutically acceptable excipient and the said added ingredient intended for bringing into contact with aqueous solution of warfarin sodium salt and/or its clathrate.

20. (New) The method according to claim 2, wherein the mixture of solid, optionally dried particles, obtained after spraying an aqueous solution of warfarin sodium salt and/or its clathrate onto solid particles of at least one pharmaceutically acceptable excipient, is mixed with at least one pharmaceutically acceptable lubricant such as preferably magnesium stearate, zinc stearate, aluminium stearate, colloidal silicon oxide, stearic acid, sodium stearyl fumarate, polyethylene glycol or sodium lauryl sulfate, used in an amount of 0.1 to 10 % by weight based on the weight of the obtained mixture, preferably with magnesium stearate used in an amount of 1 % by weight based on the weight of the mixture obtained.

21. (New) The method according to claim 2, wherein the mixture of solid, optionally dried particles, obtained after spraying an aqueous solution of warfarin sodium salt and/or its clathrate onto solid particles of at least one pharmaceutically acceptable excipient, is mixed with at least one pharmaceutically acceptable disintegrant such as preferably ultraamylpectin, sodium salt of crosslinked carboxymethylcellulose or crosslinked polyvinylpyrrolidone, used in an amount of 1 to 7 % by weight, based on the weight of the mixture obtained, preferably with sodium salt of crosslinked carboxymethylcellulose, used in an amount of 2 % by weight based on the weight of the mixture obtained.